REMARKS

The Restriction Requirement is traversed for the reasons provided herein. Applicants respectfully request that the Examiner withdraw the Restriction Requirement, and specifically the restriction between Groups I and III in view of the following remarks.

A. Examiner's objection are obviated by the claim amendments

Prior to examination, Applicants respectfully request entry of the above amendment to the claims and submit that the above amendments do not constitute new matter. Claims 34-76 will be pending on entry of the current amendments. Claims 75 and 76 are added and provide evidence for the relationship between Groups I and III — that is, the claims of each group recite the use of an antigen or set of antigens to achieve oral tolerance. Claims 46-48 are amended to recite the composition rather than the method consistent with the Examiner's notation. Support for the amendment to the claims can be found, *inter alia,* throughout the specification (*e.g.,* Example 2 at page 17) and in the claims as originally filed.

B. Response to Restriction Requirement

The outstanding Office Action requires that Applicants elect one of the following five (5) allegedly distinct inventions:

I. Claim 34-37 and 52-57, drawn to a method of screening a therapeutic drug using a lower primate infected with a human viral pathogen *(in vivo* testing of a compound), classified in class 424, subclass 9.2.

II. Claim 38, drawn to a method of screening a therapeutic drug using cells, tissues, or organs infected *in vitro* with a human viral pathogen *(in vitro* testing of a compound), classified in class 435, subclass 5.

III. Claims 39-41, 43, 49-51,58-63, and 69-74, drawn to a method for developing a therapeutic procedure in a model animal system *(in vivo* testing of a procedure), classified in class 424, subclass 9.1.

IV. Claim 42, drawn to a method for developing a therapeutic procedure, wherein the

method involves using cells, tissues or organs from a lower primate *(in vitro* testing of a procedure), classified in class 435, subclass 1.1.

V. Claims 44-48 and 64-68, drawn to a composition comprising a therapeutic drug effective in alleviating clinical manifestations of a disease caused by a human viral pathogen, classified in class unspecified, subclass unspecified.

(i) Election.

Applicant respectfully requests that the Restriction Requirement be withdrawn and that all claims be prosecuted in the same patent application. In the least, Applicant's respectfully urge the rejoinder of Groups I and III. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants hereby provisionally elect Group III, which covers claims 39-41, 43, 49-51, 58-63, and 69-74, **with traverse**. Applicants moreover reserve the right to file divisional application(s) directed to non-elected subject matter and reserve the right to petition the restriction requirement.

(ii) Groups I and III are related and not mutually exclusive.

Applicants respectfully request reconsideration of the restriction requirement in view of the following remarks. Primarily, the Office Action, in elucidating the reasons for requiring restriction between the Groups I and III alleges that the respective claims are drawn to unrelated, mutually exclusive inventions. Specifically, the Office Action provides:

> Inventions I and III are patentably distinct because the inventions are drawn to *mutually exclusive and independent methods*. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention *of Group I requires administration of a potential therapeutic drug to an infected animal, whereas the method of the invention of Group III requires carrying out a therapeutic protocol on an infected animal*. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not be steps common to the method of the invention of Group I. A potential therapeutic procedure would necessarily produce a different outcome from a potential therapeutic drug. The methods as claimed utilize different starting materials, have different method steps, and produce different effects.

> Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group III.

Office Action, page 4 (emphasis added). Contrary to that assertion, the claims of Group III (See claim 34) recite "*carrying out a therapeutic protocol on an infected animal,*" which includes the "*administration of a potential therapeutic drug to an infected animal*" as recited in the claims of Group I (See claim 34). Therefore, the embodiments of Groups I and III would not necessarily utilize different starting materials, have different method steps, and produce different effects.

Furthermore, the relationship between Groups I and III is further evidenced by claim limitations recited in added claims 75 and 76. The claims of Group I (claims 34-37, 52-57, and 75) and Group III (claims 39-41, 43, 49-51,58-63, 69-74, and 76) recite the use of an antigen or set of antigens to achieve oral tolerance. Therefore, the methods recited in the claims of Groups I and III may utilize the same or similar materials to produce the same or similar results, which may be achieved by performing the same or similar method steps. The restriction between Groups I and III is thus improper because the methods are related and are not mutually exclusive as asserted in the Office Action.

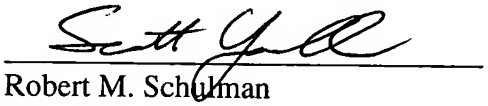
Applicants respectfully request withdrawal of the restriction requirement, and particularly the restriction between Groups I and III. Restriction between inventions is only proper when a serious search burden exists for the Examiner to search all the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. See MPEP §803.01. It is evident from overlapping method steps and similar class and subclass that a search of the subject matter of Groups I and III does not constitute a serious search burden for the Examiner.

CONCLUSION

Applicants respectfully submit that the restriction requirement is improper and request that all the claims, and particularly those of Groups I and III, *i.e.*, claims 34-37, 39-41, 43, 49-63, and 69-76, be examined for patentability. Accordingly, Applicants request withdrawal of the restriction requirement. If the Examiner believes that the prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

Dated: June 21, 2006

By: 

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